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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,718	09/22/2003	R. Stephen Brown	14453	4655

293 7590 02/22/2007

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EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	**PAPER NUMBER**
1744	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,718	BROWN ET AL.	
	Examiner	Art Unit	
	Nathan A. Bowers	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-35 and 54-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-35 and 54-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *100206*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 24, 25, 28-35 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bentsen (US 6566508) in view of Wolfbeis (US 5238809).

With respect to claims 24 and 55, Bentsen discloses a system for detecting the presence of microorganisms. The system includes a vessel in which the microorganisms in the sample are incubated. Enzymes produced by the microorganisms are allowed to react with at least one substrate in order to produce a biological molecule. An excitation light source is provided for irradiating the biological molecule, and a detector is used to detect any subsequent fluorescence from the biological molecule. The detected fluorescence is indicative of the presence of microorganisms in the sample. This is disclosed in column 2, line 54 to column 3, line 22 and column 16, line 11 to column 19, line 18. Column 24, lines 6-9 and 47-57 indicate that a controller is provided for regulating the operation of the light source. Bentsen, however, does not expressly disclose the use of a partitioning element that allows partitioning of the biological molecule thereinto.

Wolfbeis discloses a system in which the catalytic activity of enzymes is measured through the detection of emitted fluorescence. A vessel is provided in which microorganisms and enzymes are provided. Enzymes produced by the microorganisms are allowed to react with at least one substrate in order to produce a biological molecule. An optical fiber probe is inserted into the vessel for detecting the presence of the biological molecule. This is disclosed in column 9, line 63 to column 10, line 66. Column 6, lines 42-50 indicate that a partitioning element (Figure 4:23) is placed over the optical fiber probe in order to separate desired biological molecules from other compounds in the sample solution.

Bentsen and Wolfbeis are analogous art because they are from the same field of endeavor regarding enzyme detection through fluorescence.

At the time of the invention, it would have been obvious to provide the apparatus disclosed by Bentsen with an optical fiber probe comprising a partition element in order to detect fluorescence from the produced biological molecule. In column 6, lines 42-50, Wolfbeis indicates that the use of partition elements is beneficial because they are permeable to the enzyme compound that is being detected, but impermeable to unwanted cellular components. This is desirable because it insures that all detected emission light is produced by enzyme-substrate biological molecules, and not by peripheral cellular molecules. In this way, more accurate measurements regarding the amount of biological molecules (and thereby the amount of microorganisms) in the sample solution can be obtained.

With respect to claims 25 and 28, Bentsen and Wolfbeis disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. Additionally, Bentsen discloses in column 22, line 65 to column 23, line 5 and column 24, lines 7-9 and 47-57 that the apparatus is provided with control means for regulating the operation of the system, as well as control means for storing and outputting fluorescence data. A processor assembly (Figure 1:350) is provided for transmitting data electronically.

With respect to claims 29, 30 and 32, Bentsen and Wolfbeis disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. In addition, Bentsen discloses in column 17, lines 10-52 that the organism is *Escherichia coli*, and that the sample is selected from water, biological samples, food, and soil.

With respect to claims 31 and 33, Bentsen and Wolfbeis disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. Bentsen additionally indicates in column 16, lines 22-59 that beta glucuronidases and beta galacotsidases are known in the art as enzymes that are used in the detection of microorganisms. Column 3, lines 14-16 and column 16, lines 22-59 indicate that glucuronides and galactopyranosides are known in the art as acceptable substrates.

With respect to claims 34 and 35, Bentsen and Wolfbeis disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. As previously noted, Bentsen discloses in column 22, line 56 to column 23, line 5 that the system includes optical components (Figure 1:340) for monitoring fluorescence detection. Bentsen teaches that fluorogenic dyes are attached to the substrate, and incorporated into the biological molecule formed by the substrate-enzyme reaction. This is disclosed in column 10, lines 7-14. If Wolfbeis's partition element was implemented in Bentsen's microorganism detection system (as suggested in the 35 U.S.C. 103 rejection of claim 24 above), the fluorescent dye would travel through the partitioning element with the biological molecule to the detection area. As already noted, the fluorescence of the dye is detected by the detector, and the control unit uses the detected fluorescence to monitor fluorescence detection of the system.

2) Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bentsen (US 6566508) in view of Wolfbeis (US 5238809) as applied to claim 24, and further in view of Lee (US 20030222012).

Bentsen and Wolfbeis disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose the use of a removable cartridge in the vessel that is capable of containing the sample and the substrate. Bentsen and Wolfbeis do not disclose a removable cartridge containing a partitioning element.

Lee discloses a removable cartridge that comprises a mesoscale filter that is capable of partitioning cellular components in a sample. Detectable compounds are moved through the filter in an effort to remove undesirable cellular elements. The detectable compounds are then moved to a detector in order to verify their presence in the sample. This is disclosed in paragraphs [0008], [0012], [0016]-[0018] and [0045]-[0048]. Paragraph [0069] specifically states that the device is configured as a cartridge for easy insertion and removal from a vessel, and paragraph [0071] indicates that the device is used to biological microorganisms.

Bentsen, Wolfbeis and Lee are analogous art because they are from the same field of endeavor regarding microorganism detection devices.

At the time of the invention, it would have been obvious to provide the apparatus disclosed by Bentsen and Wolfbeis with a removable cartridge for containing the sample and partitioning produced biological molecules. In paragraph [0069], Lee indicates that removable cartridges are beneficial because they can easily be moved from one reaction vessel to the next. Removable cartridges are known in the art to be reusable and therefore cost effective. Lee indicates in paragraphs [0012] and [0016]-[0018] that removable cartridges that employ partitioning membranes are especially beneficial because they represent a means by which biological molecules can be separated from undesirable cellular compounds that would otherwise interfere with accurate detection procedures.

3) Claims 54, 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bentsen (US 6566508) in view of Wolfbeis (US 5238809) as applied to claims 24 and 55, and further in view of Ritts (US 20030228681).

Bentsen and Wolfbeis disclose the apparatus set forth in claim 55 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the biological molecule partitions into the portioning element while the substrate does not. Wolfbeis does not disclose that the partitioning film comprises hydrophobic polydimethylsiloxane (PDMS).

Ritts discloses a system for detecting the presence of an organism having at least one enzyme in a sample. The enzyme is introduced into a first compartment and a barrier separates the first compartment from a second compartment. Substrates positioned within the first compartment react with the enzyme and produce a detectable species that is transported across the barrier. This is described in paragraphs [004]-[0007], [0058] and [0242]-[0244]. Paragraphs [0061], [0074] and [0218] state that the barrier is a hydrophobic PDMS film.

Bentsen, Wolfbeis and Ritts are analogous art because they are from the same field of endeavor regarding detection devices.

At the time of the invention, it would have been obvious to ensure that the partitioning barrier disclosed by Wolfbeis was constructed from a hydrophobic PDMS film. PDMS is a material that is inexpensive and easily manufactured using known microfabrication techniques. Ritts teaches that PDMS is effective in allowing the diffusion of desired compounds and restricting the passage of other compounds.

Response to Arguments

Applicant's arguments filed 13 December 2006 have been fully considered but they are not persuasive.

Applicant's principle arguments are

(a) Any separation of molecules provided by the enzyme permeable membrane of Wolfbeis is based only on molecule size, which, in turn, is based on pore size of the membrane. However, such separation is merely filtering, wherein molecules smaller than the pore size will pass through the membrane, and molecules larger than the pore size will not pass through the membrane. Such separation is not selective partitioning as taught in the invention.

In response to Applicant's arguments, please consider the following comments.

It is agreed that the partition membrane of Wolfbeis operates predominantly via filtration in that molecules smaller than the pore size will pass through the membrane. However, there are no claim limitations pertaining to a "selective partitioning." The independent claim only requires a "partitioning element that allows partitioning of either said biological molecule or said at least one substrate thereinto." There are no limitations stipulating what the biological molecule and/or substrate are separated from, and the claim does not require that the biological molecules are isolated from the substrate. Wolfbeis clearly discloses a system in which enzymes, reagents and products are separated by a partitioning element from various contaminants and cell components in a sample solution.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NAB

GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER